K101827

Section 5

APR 20 2011

510(k) Summary

Applicant Name and Address	Texas Innovative Medical Devices (DBA) Skeletal Regeneration, Ltd. 14785 Omicron Dr Building 100, Suite 101 San Antonio, Texas 78245
Contact Person:	Jerry Chang Senior Director of Quality Assurance/Regulatory Affairs (210) 696-7616
Date of Summary:	January 18, 2011 (edits made) Original Submission made June 30, 2010
Name of Device:	OsteoScaf™
Trade/Proprietary Name:	OsteoScaf™
Common Name:	Bone Grafting Materials, Synthetic
Establishment Name:	OsteoScaf™
Establishment Number:	21 CFR 872.3930
Proposed Classification:	Class II
Product Code:	LYC
Panel:	Dental

Predicate Devices:

ReOSS™	Intra-Lock International, Inc	K082419
Bio-OSS™	Geistlich Biomaterials, Inc	K033815
Norian PDC™	Norian Corp	K983104
Vitoss™	Orthovita, Inc	K083033
HEALOS™	Depuy Spine, Inc	K081432

Intended Use:

OsteosScaf™ bone grafting material is indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

Device Description:

OsteoScaf™ is a synthetic osteoconductive and bioresorbable bone grafting material composed of 3-phase biodegradable polymer and calcium phosphate composite, intended to fill and/or augment intraoral/maxillofacial osseous defects. It functions in the same manner as the predicate devices. The product is available as a particulate, cylinder, or block and is provided in sterile packaging in various dosage volumes.

Summary of Technological Characteristics:

The OsteoScaf™ bone grafting material is comprised of a 3-phase composite scaffold comprising poly (lactide-co-glycolide) (PLGA) and 2 osteoclast-resorbable calcium phosphate (CaP) phases that provide the same physical characteristics as the listed predicate devices. The latter are particulates synthesized at physiological temperature and blended with the PLGA phase, and a thin layer of hydroxyapatite surface coating generated in a simulated body fluid at physiological temperature. The Device is configured as a particulate, cylinder or in a block shape and is packaged in a tray and a chevron type peel pouch for easy use. The product is irradiated to ensure sterility. The Device has a trabecular structure that is the same as the predicate devices and mimics the multidirectional interconnected porosity of human cancellous bone. The Device resorbs and is replaced with natural bone, which remodels during the healing process in the same fashion as that of the predicate devices.

Summary of Performance Testing:

Bench and animal studies were conducted to ensure that OsteoScaf™ bone grafting material met the predetermined design specifications. OsteoScaf™ has been tested for a number of chemical and physical characteristics: chemical composition, phase composition, trace of impurities, density and porosity, particle size, morphology, compressive strength and elastic modulus. All these characteristics are equivalent to those of the predicate device. OsteoScaf™ is osteoconductive and bioresorbable based on *in vivo* studies. When OsteoScaf™ is placed in direct contact with viable bone, new bone forms in apposition to the OsteoScaf™ surfaces and within the interstices of the implant. As the material resorbs, bone tissue grows into the space previously occupied by the implant. The testing performed included the following:

Test Items	Summarized Results
Chemical composition	3-phase composite of 22% (wt) PLGA, 66% Calcium phosphates and 12% hydroxyapatite.
Impurity	Testing demonstrates compliance with ASTM 1185 requirements.
Pore structure	Highly interconnected macroporous structure of larger than 80% porosity and 0.25~1.2 mm pore size similar to human cancellous bone.
Mechanical strength	The devices provides adequate handling properties and strength to ensure dimensional integrity when handled by the surgeon and delivered to bony application sites.
Degradation	All three phases of the composite can be resorbed over time through hydrolytic and/or cell-mediated degradation.
Animal studies	1) OsteoScaf™ was used to reconstruct the critical-sized defect in a rat calveria model. The result demonstrated that more new bone formed with OsteoScaf™, compared to coagulum control, after 4 weeks. 2) OsteoScaf™ gave rise to more new bone formation and faster resorption of the material than the predicate in a rat model. 3) The biomechanical testing in rat model demonstrates that OsteoScaf™ bone grafting material facilitates replacement with native bone.

Conclusion:

The Company Device (OsteoScaf™) is substantially equivalent to the predicate devices for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting. The Device is also substantially equivalent to the predicate devices in terms of material composition, geometry, and technological characteristics. The material is at least as safe and effective as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jerry Chang
Senior Director of Quality Assurance and Regulatory Affairs
Texas Innovative Medical Devices (DBA) Skeletal
4808 Research Drive
San Antonio, Texas 78240

Re: K101827
Trade/Device Name: OsteoScaf™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: March 31, 2011
Received: April 1, 2011

APR 2 0 2011

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): K101827

Device Name: OsteoScaf™

Indications for Use:

OsteoScaf™ bone grafting material is indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JS Beer DDS for Dr Susan Runner
Division Sign-Off

Office of Device Evaluation (ODE)

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